(vi) Bombardier Service Bulletin 84–28–19, Revision D, dated February 16, 2018.

(vii) Bombardier Service Bulletin 84–28–24, dated November 27, 2017.

(viii) Bombardier Service Bulletin 84–28–25, dated November 27, 2017.

(ix) Q400 Dash 8 Airplane Maintenance Manual (AMM) TR 28–145, dated November 21, 2017.

Note 1 to paragraph (p)(2)(ix): The documents identified in paragraphs (p)(2)(ix) through (xvii) of this AD do not specify a publisher name; these documents were published by Bombardier.

(x) Q400 Dash 8 AMM TR 28–146, dated November 21, 2017.

(xi) Q400 Dash 8 AMM TR 28–147, dated November 21, 2017.

(xii) Q400 Dash 8 AMM TR 28–148, dated November 24, 2017.

(xiii) Q400 Dash 8 AMM TR 28–149, dated November 27, 2017.

(xiv) Q400 Dash 8 Maintenance Task Card Manual (MTCM), Maintenance Task Card 000–28–520–704 (Config A01), Revision 42, Amendment 0002, dated November 21, 2017.

(xv) Q400 Dash 8 MTCM, Maintenance Task Card 000–28–620–704 (Config A01), Revision 42, Amendment 0002, dated November 21, 2017.

(xvi) Q400 Dash 8 Maintenance Requirements Manual (MRM) TR ALI–0192, dated April 24, 2018.

(xvii) Q400 Dash 8 MRM TR ALI–0193, dated April 24, 2018.

(3) For service information identified in this AD, contact De Havilland Aircraft of Canada Limited, Dash 8 Series Customer Response Centre, 5800 Explorer Drive, Mississauga, Ontario, L4W 5K9, Canada; telephone 855–310–1013 or 647–277–5820; email *thd@dehavilland.com;* internet *dehavilland.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on August 4, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–20805 Filed 9–26–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2017–C–6238]

Listing of Color Additives Exempt From Certification; Calcium Carbonate

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the safe use of calcium carbonate in dietary supplement tablets and capsules. We are taking this action in response to a color additive petition (CAP) submitted by Colorcon, Inc. (Colorcon or petitioner).

DATES: This rule is effective October 28, 2022. Submit either electronic or written objections and requests for a hearing on the final rule by October 27, 2022. See section XI for further information on the filing of objections. The incorporation of reference of certain material listed in this rule is approved by the Director of the Federal Register as of October 27, 2022.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 27, 2022. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–C–6238 for ''Listing of Color Additives Exempt from Certification; Calcium Carbonate.'' Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20

and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Christopher Kampmeyer, Office of Food Additive Safety (HFS–255), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1255; or Alexandra Jurewitz, Office of Regulations and Policy (HFS–024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notification published in the **Federal Register** on November 20, 2020 (85 FR 74304), we announced that we filed a color additive petition (CAP 0C0318) submitted by Colorcon, Inc., 275 Ruth Rd., Harleysville, PA 19438. The petition proposed to amend the color additive regulations in § 73.70 ''Calcium Carbonate,'' by expanding the permitted uses of calcium carbonate to include use in dietary supplement tablets and capsules, including coatings and printing inks, in amounts consistent with good manufacturing practice.

II. Background

Calcium carbonate (CAS 471–34–1) is a fine, white powder prepared either by grinding naturally occurring limestone or produced synthetically through a precipitation process using heat, water, and carbon dioxide. Calcium carbonate is slightly soluble in water and dissociates into calcium and carbonate ions in an aqueous environment. Calcium is abundant in the human body and is an integral component of bones, teeth, and other biological structures. Carbonate is also present in the human body, *e.g.,* as a critical component of the pH buffering system.

Calcium carbonate is authorized under § 73.70 for use as a color additive in soft and hard candies, mints, and in inks used on the surface of chewing gum, in amounts consistent with good manufacturing practice, except that it may not be used to color chocolate or the chocolate portion of candy, as the standards of identity for chocolate do not provide for the use of color additives. Calcium carbonate is also authorized under § 73.1070 for use as a color additive in drugs; generally, in amounts consistent with good manufacturing practice. Additionally, food grade calcium carbonate and ground limestone (consisting of not less than 94 percent calcium carbonate) are affirmed as generally recognized as safe in 21 CFR 184.1191 and 184.1409, respectively. These two regulations do not include limitations for use in food other than current good manufacturing practice, which our regulations define at § 184.1(b).

The petitioner stated that calcium carbonate complies with the specifications in the 10th edition of the Food Chemicals Codex (FCC 10), which was incorporated by reference into § 73.70 (82 FR 51554, November 7, 2017). Since this regulation became effective, the 13th edition of the FCC (FCC 13) has published. The specifications for calcium carbonate and ground limestone are the same in both FCC 10 and FCC 13. Therefore, we are updating our incorporation by reference to FCC 13. In an email dated May 26, 2022, the petitioner concurred with updating the FCC reference from FCC 10 to FCC 13.

The petitioner concluded that the amount of calcium carbonate petitioned for use in dietary supplement tablets and capsules is self-limiting because the addition of the color additive above a certain level would be uneconomical and/or have adverse consequences on the quality of the dietary supplements. Because the petitioner concluded that the amount of calcium carbonate used as a color additive in dietary supplement tablets and capsules would be self-limiting, they did not propose any tolerances or other limitations. We determined there is no need for a specific upper limit for this use of calcium carbonate (Ref. 1).

III. Safety Evaluation

Under section 721(b)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379e(b)(4)), a color additive may not be listed for a particular use unless the data and information available to FDA establish that the color additive is safe for that use. Our color additive regulations at 21 CFR 70.3(i) define ''safe'' to mean that there is convincing evidence establishing with reasonable certainty that no harm will result from the intended use of the color additive.

To establish with reasonable certainty that a color additive intended for use in foods is not harmful under its intended conditions of use, we consider the projected human dietary exposure to the color additive; the additive's toxicological data; and other relevant information (such as published literature) available to us. We compare the estimated dietary exposure, or estimated daily intake (EDI), of the color additive from all dietary sources to an acceptable daily intake (ADI) level established by toxicological data. The EDI is determined by projections based on the amount of the color additive proposed for use in particular foods and on data regarding the amount consumed from all sources of the color additive. We commonly use the EDI for the 90th percentile consumer of a color additive as a measure of high chronic exposure.

IV. Safety of the Petitioned Use of the Color Additive

A. Dietary Exposure Estimate

The petitioner estimates that the amount of calcium carbonate as a color additive in dietary supplements would not exceed 24 milligrams (mg) per dietary supplement (Ref. 2). The petitioner used data for dietary supplements from the 2011–2014 National Health and Nutrition Examination Survey (NHANES) to estimate dietary exposure to calcium carbonate and elemental calcium from the proposed use. From the NHANES data, the petitioner determined that the U.S. population aged 2 years and older consumes two dietary supplements in a 24-hour period at the mean and five at the 90th percentile. We note that these values could represent two or five of the same or different dietary supplements. In estimating dietary exposure, the petitioner assumed that all dietary supplements consumed would contain calcium carbonate as a color additive and that each dietary supplement consumed contains 24 mg calcium carbonate. This results in a dietary exposure estimate to calcium carbonate of 48 milligrams/person/day (mg/p/d) at the mean and 120 mg/p/d at the 90th percentile. Because calcium carbonate is comprised of 40 percent calcium, the petitioner noted that the maximum dietary exposure to calcium from this use of calcium carbonate is estimated to be 19 mg/p/d at the mean and 48 mg/p/d at the 90th percentile.

The petitioner stated that the maximum amount of calcium carbonate deposited as a printing ink on the surface of the dietary supplement would

be 0.009 mg, which corresponds to approximately 0.004 mg of calcium per dietary supplement. The petitioner concluded that the contribution to the dietary exposure from use in printing ink on the surface of dietary supplements is accounted for in the dietary exposure estimate for the use of calcium carbonate as a color additive at the maximum proposed use level in dietary supplements. FDA concurred with this approach regarding the dietary exposure estimate for calcium and calcium carbonate from the petitioned uses of calcium carbonate (Ref. 2).

FDA previously determined the cumulative estimated dietary intake (CEDI) for calcium from all sources to be 1,150 mg/p/d at the mean and 1,925 mg/p/d at the 90th percentile for the U.S. population aged 2 years and older (Ref. 3). The petitioner summed FDA's mean cumulative dietary exposure to calcium (1,150 mg/p/d) (Ref. 3) with the mean dietary exposure to calcium from the petitioned uses (19 mg/p/d) (Ref. 2) to estimate a revised mean CEDI for elemental calcium from the existing uses as well as the petitioned use of calcium carbonate as a color additive in dietary supplement tablets and capsules, including coatings and printing inks. This resulted in a mean CEDI for calcium of 1,169 mg/p/d for the U.S. population aged 2 years and older. Using an analogous approach, the 90th percentile CEDI for calcium, determined previously (1,925 mg/p/d; Ref. 3), was summed with the 90th percentile value (48 mg/p/d) from the petitioned uses to derive an upper bound 90th percentile CEDI for calcium of <2,000 mg/p/d for the U.S. population aged 2 years and older (Ref. 2).

B. Toxicological Considerations

To support the safety of the petitioned use of calcium carbonate, the petitioner noted that calcium carbonate and ground limestone are affirmed as generally recognized as safe under §§ 184.1191 and 184.1409, respectively. The petition referenced FDA's safety review of calcium carbonate in CAP 6C0307 (Ref. 4), which resulted in FDA's listing of calcium carbonate in § 73.70. Calcium carbonate can dissociate into calcium and carbonate ions in aqueous environments, making those two ions relevant to a safety evaluation of ingested calcium carbonate. Based on carbonate's chemical structure and physiological functions, no further safety analysis of carbonate exposure was necessary (Ref. 4). FDA also considered safety evaluations by the Institute of Medicine (IOM) and safety information resulting from a search of the published literature (Ref. 4). In the IOM's 2011 report on dietary reference intakes for calcium and vitamin D, the IOM updated recommended tolerable upper limits (ULs) for calcium ranging from 2,000 to 3,000 mg/p/d for the U.S. population aged 1 year and older, based on a comprehensive literature review (Ref. 5). The IOM considered the UL as the highest average daily exposure that is likely to pose no risk of adverse effects to almost all individuals in the general population (Ref. 5).

We conducted a search of the literature from January 2016 until December 2021 to identify publications germane to our safety evaluation using several different databases (*i.e.,* PubMed, Web of Science and ToxNet). We reviewed the articles found in this search and other relevant studies available to FDA on the safety of calcium and calcium carbonate (Ref. 6). We also noted that in our previous safety review (Ref. 4) we determined that no further safety analysis of carbonate was necessary, based on its chemical structure and physiological functions (Ref. 6).

Based on our review, we considered the UL established by IOM for calcium (2,000 mg/p/d) to remain an appropriate benchmark for assessing the safety of dietary exposure to calcium from the petitioned use of calcium carbonate (Ref. 6). For the U.S. population aged 2 years and older, the dietary exposure estimate at the 90th percentile is below the IOM's UL of 2,000 mg/p/d. Additionally, the body of literature on calcium carbonate and calcium does not present evidence of safety concerns at the expected dietary exposure (Ref. 6). Based on our review of the recently published literature, and because the 90th percentile dietary exposure to calcium from all dietary sources, including the petitioned uses of calcium carbonate, is less than the UL determined by IOM, the dietary exposure to calcium from the proposed use of calcium carbonate as a color additive in dietary supplement tablets and capsules, including coatings and printing inks, does not raise safety concerns (Ref. 6). Therefore, we conclude that there is a reasonable certainty of no harm from this proposed use as a color additive.

V. Incorporation by Reference

FDA is incorporating by reference the monographs for calcium carbonate and limestone, ground from the Food Chemicals Codex, 13th ed., 2022, which was approved by the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may purchase a copy of the material from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852, 1–800–227–8772, *https://www.usp.org.* You may inspect a copy at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, between 9 a.m. and 4 p.m., Monday through Friday. Because materials incorporated by reference will no longer be available at FDA's main library, we are revising § 73.70 to update the location where referenced materials cited in FDA regulations can be found; the new location will be at the Dockets Management Staff.

The FCC monographs establish a standard for purity and identity for calcium carbonate. The monographs provide specifications and analytical methodologies used to identify the substance and establish acceptable purity criteria. The current color additive regulation for the use of calcium carbonate (§ 73.70) indicates that the additive must meet the specifications in the FCC 10. The most current version of the FCC is the FCC 13, and the specifications for calcium carbonate in FCC 13 are identical to those in FCC 10. Therefore, we are amending § 73.70 by adopting, and incorporating by reference, the specifications for calcium carbonate and ground limestone in FCC 13 in place of FCC 10.

VI. Conclusion

Based on the data and information in the petition and other available relevant information, we conclude that the petitioned use of calcium carbonate for use as a color additive in dietary supplement tablets and capsules, including coatings and printing inks, is safe. We further conclude that the color additive will achieve its intended technical effect and is suitable for the petitioned use. Therefore, we are amending the color additive regulations in part 73 to provide for the safe use of this color additive as set forth in this document. In addition, based on the factors in 21 CFR 71.20(b), we conclude that batch certification of calcium carbonate, proposed for use as a color additive in dietary supplement tablets and capsules, including coatings and printing inks, is not necessary for the protection of public health (Ref. 1).

VII. Public Disclosure

In accordance with § 71.15, the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure

(see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, we will delete from the documents any materials that are not available for public disclosure.

VIII. Analysis of Environmental Impact

As stated in the November 20, 2020, **Federal Register** notification of filing, the petitioner claimed that this action is categorically excluded under § 25.32(k) because the substance is intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food. We further stated that if FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. We did not receive any new information or comments regarding this claim of categorical exclusion. We considered the petitioner's claim of categorical exclusion and determined that this action is categorically excluded under § 25.32(k). Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Section 301(ll) of the FD&C Act

Our review of this petition was limited to section 721 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) to (4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this color additive. Accordingly, this final rule should not be construed to be a statement that a food containing this color additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all color additive final rules that pertain to food and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

XI. Objections

This rule is effective as shown in the **DATES** section, except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.* We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

* 1. Memorandum from N. Hepp, Color Technology Branch, Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition (CFSAN), FDA to C. Kampmeyer, Division of Food Ingredients (DFI), Office of Food Additive Safety (OFAS), CFSAN, FDA, May 11, 2022.
* 2. Memorandum from D. Doell, Chemistry Review Team, DFI, OFAS, CFSAN, FDA to C. Kampmeyer, DFI, OFAS, CFSAN, FDA, May 11, 2022.
* 3. Memorandum from D. Doell, Division of Petition Review (DPR), OFAS, CFSAN, FDA to J. Kidwell, DPR, OFAS, CFSAN, FDA, February 16, 2017.
* 4. Memorandum from T.S. Thurmond, DPR, OFAS, CFSAN, FDA to J. Kidwell, DPR, OFAS, CFSAN, FDA, February 17, 2017.
5. Committee to Review Dietary Reference Intakes for Vitamin D and Calcium, Food and Nutrition Board, Institute of Medicine, ''Dietary Reference Intakes for Calcium and Vitamin D,'' National Academies Press, Washington, DC 2011. Available at *https://www.nap.edu/read/13050/chapter/1* (accessed July 27, 2021).
* 6. Memorandum from R. Chanderbhan, Toxicology Review Team, DFI, OFAS, CFSAN, FDA to C. Kampmeyer, DFI, OFAS, CFSAN, FDA, May 11, 2022.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Incorporation by reference, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Amend § 73.70 by revising paragraphs (b) and (c) and adding paragraph (f) to read as follows:

§ 73.70 Calcium carbonate.

* * * * *

(b) *Specifications.* Calcium carbonate must meet the specifications given in calcium carbonate (FCC 13) and limestone, ground (FCC 13).

(c) *Uses and restrictions.* Calcium carbonate may be safely used in amounts consistent with good manufacturing practice to color dietary supplement tablets and capsules (including coatings and printing inks), soft and hard candies and mints, and in inks used on the surface of chewing gum, except that it may not be used to color chocolate for which standards of identity have been promulgated under section 401 of the Federal Food, Drug,

and Cosmetic Act unless added color is authorized by such standards.

* * * * *

(f) *Incorporation by reference.* Material listed in this paragraph (f) is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration and at the National Archives and Records Administration (NARA). Contact the Food and Drug Administration between 9 a.m. and 4 p.m., Monday through Friday at: Dockets Management Staff, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. For information on the availability of this material at NARA, email: *fr.inspection@nara.gov;* website: *www.archives.gov/federal-register/cfr/ibr-locations.html.* You may obtain the material from the U.S. Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852; website: *www.usp.org.*

(1) Limestone, Ground, *Food Chemicals Codex,* 13th edition, effective June 1, 2022 (FCC 13).

(2) Calcium Carbonate, *Food Chemicals Codex,* 13th edition, effective June 1, 2022 (FCC 13).

Dated: September 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20819 Filed 9–26–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 560

Publication of Iranian Transactions and Sanctions Regulations Web General License M and Subsequent Iterations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of web general licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing three general licenses (GLs) issued in the Iranian Transactions and Sanctions program: GLs M, M–1, and M–2, each of which was previously made available on OFAC's website.

DATES: GL M–2 was issued on August 25, 2022. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *www.treas.gov/ofac.*

Background

On October 29, 2020, OFAC issued GL M to authorize certain transactions otherwise prohibited by the Iranian Transaction and Sanctions Regulations, 31 CFR part 560. GL M had an expiration date of September 1, 2021. On August 24, 2021, OFAC issued GL M–1, which replaced and superseded GL M and had an expiration date of September 1, 2022. On August 25, 2022, OFAC issued GL M–2, which replaced and superseded GL M–1 and has an expiration date of September 1, 2023. All three GLs were made available on OFAC's website (*www.treas.gov/ofac*) at the time of publication. The text of GLs M, M–1, and M–2 is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Iranian Transactions and Sanctions Regulations

31 CFR Part 560

GENERAL LICENSE M

Authorizing the Exportation of Certain Graduate Level Educational Services and Software

(a) Except as provided in paragraph (c) of this general license, accredited graduate and undergraduate degree-granting academic institutions located in the United States (collectively, ''U.S. academic institutions''), including their contractors, are authorized through 12:01 a.m. eastern daylight time, September 1, 2021, to engage in the following activities with respect to Iranian students described in paragraph (b):

(1) *Online Educational Services.* The provision of online educational services related to graduate educational courses, provided that the courses are the equivalent of courses ordinarily required for the completion of graduate degree programs in the humanities, social sciences, law, or business, or are introductory science, technology, engineering, or mathematics courses ordinarily required for the completion of graduate degree programs in the humanities, social sciences, law, or business, and participation in all activities related to the provision of such online educational services to Iranian students described in paragraph (b).

(2) *Exportation of Software.* The exportation of software to Iranian students described in paragraph (b) in order to facilitate participation in the activities authorized in (i) paragraph (a) of this general license or (ii) paragraph (b)(1)(iii) of Iran General License G, provided such software is designated as EAR99 under the Export Administration Regulations, 15 CFR parts 730 through 774 (EAR), or constitutes information or software not subject to the EAR pursuant to 15 CFR 734.3(b)(3).

(b) Iranian students referred to in paragraph (a) are individuals located in Iran, or located outside Iran but who are ordinarily resident in Iran, who are eligible for non-immigrant classification under categories F (students) or M (non-academic students), and have been granted a non-immigrant visa by the U.S. State Department, but are not physically present in the United States due to the COVID–19 pandemic.

(c) This general license does not authorize the exportation or reexportation of any services or software to the Government of Iran or any other person whose property and interests in property are blocked pursuant to 31 CFR chapter V.

Note 1 to General License M: The importation from Iran and the exportation to Iran of information or informational materials, as defined in 31 CFR 560.315, whether commercial or otherwise, regardless of format or medium of transmission, are exempt from the prohibitions of 31 CFR part 560. *See* 31 CFR 560.210(c).

Note 2 to General License M: U.S. persons are authorized to engage in the exportation of certain educational services under Iran General License G, which was issued pursuant to 31 CFR part 560, and to export, reexport, and provide certain services, software, and hardware incident to personal communications under Iran General License D–1, which was issued pursuant to 31 CFR part 560.

Andrea Gacki,

Director, Office of Foreign Assets Control.

Dated: October 29, 2020.

OFFICE OF FOREIGN ASSETS CONTROL

Iranian Transactions and Sanctions Regulations

31 CFR Part 560

GENERAL LICENSE M–1

Authorizing the Exportation of Certain Graduate Level Educational Services and Software

(a) Except as provided in paragraph (c) of this general license, accredited graduate and undergraduate degree-granting academic institutions located in the United States (collectively, ''U.S. academic institutions''), including their contractors, are authorized through 12:01 a.m. eastern daylight time, September 1, 2022, to engage in the following activities with respect to Iranian students described in paragraph (b):

(1) *Online Educational Services.* The provision of online educational services related to graduate educational courses, provided that the courses are the equivalent of courses ordinarily required for the completion of graduate degree programs in the humanities, social sciences, law, or